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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624,443

07/22/2003

Thomas G. Rehberger

AGP-32578-1

6437

56080 7590 02/22/2007
WHYTE HIRSCHBOECK DUDEK S.C.
ONE EAST MAIN STREET
SUITE 300
MADISON, WI 53703-3300

EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/624,443	Applicant(s) REHBERGER ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 36-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-35, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 1/0/07 is acknowledged. Claims 19-35 and 40-41 are being considered on the merits.

Claims 1-18 and 36-39 are withdrawn from consideration as directed to a non-elected invention.

Specification

The amendment filed 1/0/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The substitution of Figure I with Figures I-A and I-B in the Drawings..

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-35 and 40-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for Figure I-A and I-B now of record. There is no clear correlation between the new Figure I-A or Figure I-B and Figure I as filed. Applicant has not indicated the correction of an error in the original figure, but rather a further analysis of the data, which was not in possession of applicant at the time the claimed invention was made, as evidenced by the instant written disclosure.

Response to Arguments

Applicant's arguments and the Rehberger declaration have been fully considered but they are not deemed to be persuasive.

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The declaration clearly shows that the figure I-B pertains to an entirely new analysis of data not present in the as-filed specification. Therefore, the material added constitutes the addition of new data to the specification.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-35 and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague, indefinite and confusing in the recitation of “that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figures IA, Figure IB, and Table 6. The genus of *Lactobacillus* strains intended to be encompassed by this terminology cannot be readily assessed. Applicant now indicates there is there one Profile I, yet the claim reads on various “Profile I” variants by virtue of the recitation “a Profile I”.

In addition, the new Figures cannot be readily compared with the figure as filed, which is not clearly legible. In addition, the new Figures provide data beyond that provided in the as-filed specification. Thus, the strains encompassed by the claim designated language cannot be reliably identified.

Table 6 provides strain designations and species designations, but the correlation with Profile I is unclear. The Figure and Table are not informative regarding the specific properties of the strains intended to be claimed.

The reasons or criteria for designating pigs as “representative” for inclusion in Table 6 data are not set forth with any particularity on the record.

Claim 26 is vague and indefinite in the recitation of a “milk replacer”, since the nature of the material intended is unclear. Milk can be replaced by water or any other liquid.

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Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Regarding the recitation of "milk replacer" and the extensive listing of patents presented, no clear correlation has been shown regarding the use of this language in the recited patents and the instant invention. Therefore, the listing presented does not clarify the material intended by "milk replacer" herein with any specificity. Applicants citation of previously granted patents is not persuasive regarding the prosecution of the present application, since each patent application is prosecuted on its own merits and what was done in a previous case does not constitute imprimatur for the prosecution of further cases. *In re Gyurik*, 596 F.2d 1012, 201 USPQ 552 (CCPA 1979); *In re Attwood*, 267 F.2d 954, 122 USPQ 378 (CCPA 1959); *In re Freedlander*, 136 F.2d 759, 760, 58 USPQ 402, 403 (CCPA 1943).

The rejection under 35 U.S.C 112, first paragraph regarding deposit only is withdrawn in view of the Rehberger declaration..

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 19-21, 23-28, 30-33, 34-35 and 40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tannock *et al.*.

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 which has been optionally isolated from a pig.

Tannock *et al.* discloses at least one *Lactobacillus* strain that has a Profile I which has been optionally isolated from a pig. See, e.g., page 1313. The strains are identified as *L. fermentum*.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel presents the bald argument that the reference strain does not possess the required profile. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

In addition, the recitation of functional limitations will not *per se* render an undefined grouping of bacteria patentable based on the finding of a few strains. Knowledge in the art regarding a property such as a specific Profile based on certain digests is not an issue. Such a property is inherent in the strains.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999)). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.*; see also *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003).

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(rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Moreover, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being isolated from a pig, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing anticipation/non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 19-21, 23-28, 30-33, 34-35 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krause *et al.*, (Anaerobe (1997), 3(5), 317-325).

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa I*, *Not I* and *Xba I* digests, as shown in Figure I-A and I-B and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., Table I, page 320) since it is presumed to have Profile I based on *Apa I*, *Not I* and *Xba I* digests, as shown in Figure I-A and I-B and Table 6 because it has been isolated from the gastrointestinal tract of a pig. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is of the same class as that of the microorganism claimed., including the same species.. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed

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microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel presents the bald argument that the reference strain does not possess the required profile. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

In addition, the recitation of functional limitations will not *per se* render an undefined grouping of bacteria patentable based on the finding of a few strains. Knowledge in the art regarding a property such as a specific Profile based on certain digests is not an issue. Such a property is inherent in the strains.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999)). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Moreover, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent,

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from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being isolated from a pig, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing anticipation/non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 19-21, 23-28, 30-33, 34-35 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Benoit *et al.*, (Current Microbiology Volume 28, Number 1 Date: January 1994 Pages: 53 - 61).

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., Table I, page 54) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 because it has been isolated from pig. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is of the same class as that of the microorganism claimed., including the same species.. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

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Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel presents the bald argument that the reference strain does not possess the required profile. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

In addition, the recitation of functional limitations will not *per se* render an undefined grouping of bacteria patentable based on the finding of a few strains. Knowledge in the art regarding a property such as a specific Profile based on certain digests is not an issue. Such a property is inherent in the strains.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Moreover, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being isolated from a pig, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of

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establishing anticipation/non-obviousness by objective evidence shifted to Applicants.

Applicants have not met that burden.

Claims 19-21, 23-28, 30-33, 34-35 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Coventry et al., (J. Appl. Bacteriol, 1996 Jan;80(1):91-8.) The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., col. 1, page 91) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 because it has been isolated from pig. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is of the same class as that of the microorganism claimed., including the same species..

Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel presents the bald argument that the reference strain does not possess the required profile. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

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In addition, the recitation of functional limitations will not *per se* render an undefined grouping of bacteria patentable based on the finding of a few strains. Knowledge in the art regarding a property such as a specific Profile based on certain digests is not an issue. Such a property is inherent in the strains.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates.” *Id.* (quoting *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999)). Moreover, “[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Moreover, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being isolated from a pig, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing anticipation/non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 19-21, 23-28, 30-33, 34-35 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schutz, *et al.*, (System. Appl. Microbiol., 5:169 (1984)). The claims are drawn to at least one *Lactobacillus*

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strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., page 170) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 because it belongs to the same species as included in the claimed invention and is considered to anticipate the claimed microorganism. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel presents the bald argument that the reference strain does not possess the required profile. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

In addition, the recitation of functional limitations will not *per se* render an undefined grouping of bacteria patentable based on the finding of a few strains. Knowledge in the art regarding a property such as a specific Profile based on certain digests is not an issue. Such a property is inherent in the strains.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art

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reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates.” *Id.* (quoting *MEHL/Biophile Int’l Corp. v. Milgram*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, “[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Moreover, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being isolated from a pig, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing anticipation/non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 19-21, 23-28, 30-33, 34-35 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewus, et al. (Detection of bacteriocins produced by lactic acid bacteria, *Journal of Microbiological Methods* 13(2) 145-150. 1991.)

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 which has been optionally isolated from a pig.

The cited reference discloses at least one *Lactobacillus* strain that which appears to be identical to the presently claimed strain (see, e.g., Table 1, page 147) since it is presumed to have Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 because it belongs to the same species as included in the claimed invention and is considered to

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anticipate the claimed microorganism. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel presents the bald argument that the reference strain does not possess the required profile. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

In addition, the recitation of functional limitations will not *per se* render an undefined grouping of bacteria patentable based on the finding of a few strains. Knowledge in the art regarding a property such as a specific Profile based on certain digests is not an issue. Such a property is inherent in the strains.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *Id.* (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999)). Moreover, "[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of

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ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Id.*; see also *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

Moreover, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being isolated from a pig, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing anticipation/non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 19-22, 23-32, 34-35 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tannock *et al.* taken with Krause *et al.*, Craig *et al.* (U.S. Patent No. 5,795,602) and Iritani *et al.* (U.S. Patent No. 6,090,416)

The claims are drawn to at least one *Lactobacillus* strain that has a Profile I based on *Apa* I, *Not* I and *Xba* I digests, as shown in Figure I-A and I-B and Table 6 which has been optionally isolated from a pig.

Each of Tannock *et al.* and Krause *et al.* discloses at least one *Lactobacillus* strain that has a Profile I which has been isolated from the gastrointestinal tract of a pig. See, e.g., page 1313 and 320, respectively. The strains are identified as *L. fermentum* or *L. brevis*. At least the strains of Tannock *et al.* are shown to possess a Profile I. It is noted that agar is a gel paste at least to some extent.

The references may differ from the claimed invention in that a gruel feed is not taught as a carrier for at least one *Lactobacillus* strain. However, Iritani *et al.* adequately demonstrate that fermented compositions are provided in the form of gruel, which material also may act as a milk replacer upon dilution. See, e.g., Examples. In addition, Craig *et al.* disclose the benefits of probiotics added to milk, which one of ordinary skill in the art would have recognized to be

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similarly beneficial when added to milk replacers or to other food materials. See, e.g., col. 2, lines 50-60 and col. 5, lines 15-27.

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the products of Tannock *et al.* and Krause *et al.* by providing the probiotics disclosed by the references in conjunction with a gruel composition or a diluted gruel composition as suggested by the teachings of Iritani *et al.* and Craig *et al.* for the expected benefit of providing required nutrients in combination with probiotics known to favorably affect the gastrointestinal flora by displacing deleterious microorganisms at least by competitive exclusion.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel presents the bald argument that the reference strains do not possess the required profile. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

In addition, the recitation of functional limitations will not *per se* render an undefined grouping of bacteria patentable based on the finding of a few strains.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being isolated from a pig, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing anticipation/non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

No claim is allowed.

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Claims 22, 33 and 41 are free of the art of record. There would have been no motivation for one of ordinary skill in the art to provide a strain of *L. brevis* having all of the identifying characteristics of strain 1E-1, deposited at the ATCC under accession number PTA-6509 at the time the claimed invention was made..

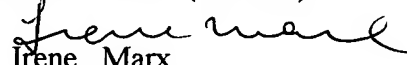
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
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